

**Statement of Chairman Tom Davis**  
**Committee on Government Reform Hearing**  
**“The Nation’s Flu Shot Shortage: How it Happened and Where We Go from Here”**  
**October 8, 2004**

Good morning. I want to welcome everyone to today’s oversight hearing regarding recent developments in the U.S. influenza vaccine supply.

As many of you know, a major flu vaccine manufacturer announced on Tuesday it would be unable to deliver any of its flu vaccine to the U.S. British regulators suspended the manufacturer’s license and held up the doses destined for the United States because at least some of the supply was contaminated.

The loss of the Chiron flu vaccine poses a serious challenge to the U.S. vaccine supply for the upcoming flu season. Chiron was to export between 46-48 million flu shots this year to the United States, almost half of our nation’s supply. The Department of Health and Human Services (HHS) had planned for a vaccine supply of about 100 million doses this season, after a demand of about 87 million doses last flu season.

Today we will examine the contributing factors that led to the severe flu vaccine shortage, the public health implications of the vaccine shortage, and the U.S. government and vaccine manufacture’s plan to address this problem. Our government witnesses are here today to reassure and inform the public.

The public health implications of this development are potentially enormous. Every year approximately 36,000 people die and 200,000 people are hospitalized due to complications from influenza. With a significant shortage of vaccines, the number of people who die from or are hospitalized for influenza could increase drastically this year. The Centers for Disease Control and Prevention (CDC) issued interim recommendations for influenza vaccination on October 5, 2004. They give priority for vaccination with Fluzone—the primary vaccine that remains available—to the “high-risk” population. A nasal spray is another alternative, but there will be at most 2 million doses ready for distribution this year.

As a result of the shortage, millions of healthy people and even many in the high-risk population will have to forego vaccination. We’ve been telling people for years now that the flu is not something to take lightly. It’s no wonder phones at hospitals, clinics and doctors’ offices have been ringing off the hook this week. Vaccination clinics with shuttered doors do not inspire confidence or trust. People want to know how this happened. They want to know what it means for them and their families. They want to know how we’re going to make sure it doesn’t happen again.

In the short term, coordination and cooperation between federal, state and local public health providers will be crucial. It will be more important than ever to identify individuals who fall within the high-risk population and ensure they receive priority. We

will collectively have to grapple with the public's understandable frustration and feelings of helplessness.

Preparing for the annual flu season highlights the importance of strong cooperation between different health agencies and private sector companies at all levels. However, this year's vaccine shortage starkly underscores the need to ensure that adequate production capabilities exist. We are not here today to point fingers. But we go into today's hearing already concluding that the current system is fatally flawed.

At a Committee hearing we held last February, witnesses discussed the possibility of a similar situation unfolding. The Committee was concerned that Chiron did not have a manufacturing plant located within the U.S. It was theorized that, should a flu pandemic occur, the UK could nationalize Chiron's vaccine supply, resulting in the loss of half of the U.S. flu vaccine supply. With only a few vaccine manufacturers producing flu vaccines each year, we concluded then, and we reiterate today: we need to consider what can be done to strengthen the market and increase production capabilities.

The current vaccine shortage begs the question: Do we need new mechanisms, new incentives, to guarantee that an adequate number of safe and effective flu vaccines are produced and delivered annually?

Questions continue to mount, and hopefully today some will be answered. Why did both Chiron and U.S. officials anticipate that only 4 to 8 million doses would be lost? Why did they not know before Tuesday that a license suspension was possible? Are any of the Chiron doses salvageable?

Our witnesses today will also discuss the factors contributing to the flu vaccine shortage, how the government and vaccine manufacturers will respond to and manage this crisis, and the steps that must be taken to be prepared for next year's flu season. I look forward to a constructive dialogue on this matter. I know we all share the same goal at the end of the day—a public health system prepared to deal with the annual influenza season.